INTEROFFICE COMMUNICATION

WASHINGTON STATE PATROL

TO: Dr. Fiona J. Couper, Toxicology Laboratory Division

FROM: Sergeant Ken Denton, Impaired Driving Section

SUBJECT: Software Approval for Draeger Alcotest 9510 Instrument

DATE: September 30, 2014 **FILE:**

The Washington State Patrol (WSP) Breath Test Program (BTP) is seeking approval of software for the Draeger Alcotest 9510 (Draeger), evidential breath test instrument. The Draeger has multiple software components and a brief description of each is provided below.

- Windows CE (WinCE) 5.5 8322797
- Measurement System Software 8322798 0.7
- Configuration File Software 8322796 2.3
- Bootloader 1.5 8323536

Windows CE (WinCE) –Version Number: 5.5 8322797

The Windows CE operating system handles the collection of touchscreen, card reader, keyboard inputs, display and external printer outputs, along with communication between the instrument and the host computer during polling. The WinCE software does not display a version number on the evidential breath printout or on the Draeger Alcotest 9510 Calibration/Adjustment Record. Any updates to this software would be provided to the BTP by the manufacturer. The manufacturer has advised that any change to this software would not affect any analytical outputs of the instrument. Based on this, we recommend that a new calibration procedure is not necessary if this software is updated.

This software version number is stored in memory on the instrument and may be displayed by personnel that have access to the technician USB keys. Only those trained personnel will be able to see the version on the instrument display, it will not be printed on any of the regular documents generated by the instrument.

Measurement System Software –Version Number: 8322798 0.7

This is identified on the instrument printouts as follows:

- Draeger Alcotest 9510 Calibration Adjustment Record: **"SOFTWARE VER."**
- Evidential breath test documents: **"SOFTWARE VERSION"**

The version number (8322798 0.7) is the version which was utilized for the validation testing completed in the fall of 2013. During our testing of the instruments and software

we found it performed as expected, yielding results that were accurate, precise and reliable.

This software is often referred to as the M16 Processor and provides the instructions that run and operate the analytical microprocessor. The microprocessor manages the various sensor inputs, algorithms and computations which produce the results, and the measurement sequence.

If this software is updated from the identified version number, a series of validation tests will be completed on a select number of instruments to ensure proper functionality. This will include a new Quality Assurance Procedure (QAP) which will be completed per the Breath Test Program Technical Manual procedures. After the testing is completed and if found to be acceptable, a new approval request will be submitted.

Configuration File Software –Version Number: 8322796 2.3

This is identified on the instrument printouts as follows:

- Draeger Alcotest 9510 Calibration/Adjustment Record: **"CONFIG. VER."**
- Evidential breath test documents: **"CONFIGURATION VERSION"**

The version number (8322796 2.3) is the version which was utilized for the validation testing completed in the fall of 2013. During our testing of the instruments and software we found it performed as expected, yielding results that were accurate, precise and reliable.

This set of files contains the specific settings and details for the WinCE operating system and Measurement System Software that controls the instrument behavior per requested specifications. These settings are separated into two different files. The first file (Approval, APF Configuration files) contains the analytical parameters and instructions which relate to the analytical performance and measurement procedures for the device. The second file (non-approval, NAPF Configuration files) contains administrative settings and information for the WinCE operating system and the Measurement System Software.

If this software is updated from the identified version number, a series of validation tests will be completed on a select number of instruments to ensure proper functionality. This will include a new Quality Assurance Procedure (QAP) which will be completed per the Breath Test Program Technical Manual procedures. After the testing is completed and if found to be acceptable, a new approval request will be submitted.

Bootloader Software –Version Number: 1.5 8323536

The Bootloader Software contains a small set of instructions which are executed immediately when the instrument is powered on. These commands provide start-up information to the microprocessor and do not influence any customer specific functionality of the instrument.

The Bootloader Software has no effect on the instrument's analytical functionality. Because the analytical functionality would not be affected by any Bootloader Software update, we recommend that no future Bootloader Software approval would be necessary. This software does not display a version number on the evidential breath printout or on the Draeger Alcotest 9510 Calibration/Adjustment Record. Much like the WinCE operating system, the version number is only seen on the display screen by those with access rights.

Instrument Functionality

This section contains the different functional features of the instrument design. These will be divided into two categories: Manufacturer Design and Specifications and WSP Specific Performance Requirements.

Manufacturer Design and Specifications

The Draeger Alcotest 9510 is manufactured by Draeger Safety Diagnostics Inc. The instrument is listed on the National Highway Traffic Safety Administration (NHTSA) Conforming Products List (CPL). The instrument has a dual measurement system: infrared at 9.5 µm and electrochemical (also referred to as fuel cell).

- The central part of the measuring system is the infrared absorption cuvette. The cuvette contains a sample chamber with a volume of 70mL. There are gold-coated parabolic mirrors, an electronically modulated infrared source as well as a pyro detector with an integrated infrared filter. The cuvette is heated to a minimum of 39° Celsius and maximum of 50°Celsius to prevent condensation in the chamber. This temperature is monitored by the Measurement System Software and any attempt to test on the instrument when the temperature is outside of this range will be prohibited by the software. The Draeger measures ethanol at 9.5µm. The instrument was designed at this level of the infrared spectrum because this area of the spectrum virtually eliminates the possibility of cross-contamination from interfering compounds.

- The other measuring feature of the Draeger is the electrochemical (fuel cell) detection. The fuel cell consists of a porous, acidic membrane (electrolyte), which is laminated by two platinum black plates. An electric wire is attached to each of the platinum plates. This assembly is packed into a sealed plastic housing which has a small gas inlet leading into the sample chamber of the instrument where breath is introduced. A piston on top of the cuvette draws a 1cc sample into the fuel cell. One of the platinum plates will be exposed to the breath sample. Any ethanol in the breath will create a chemical reaction and produce an electrical, measured current between the two platinum plates. This measured current becomes the usable indicator of the amount of ethanol consumed by the fuel cell and is directly proportional to an ethanol concentration in a breath sample. After processing, a quantitative result is determined. A rise in BrAC will result in a proportionate increase in voltage.

  Other alcohols (isopropanol and methanol) will also react in the cell but because the chemistry is different the rate of reaction is also different.

Data Entry Requirements:

The Draeger is designed to collect data entry manually and by scanning the operator permit card and WA driver's license. Below are the Data Entry fields that are to be completed.

Data Entry Fields	How Data to be entered and/or collected
Observation start time	Entered by operator the time in 24 hr format.
Operator observed subject entire time?	Yes or No selected from display screen by operator. If operator selects "No" the instrument invalidates the test sequence.
Subject smoke, vomit, or put anything in mouth?	Yes or No selected from display screen by operator. If operator selects "Yes" the instrument invalidates the test sequence.
Citation/Case Number	Entered by operator if known.
County of Arrest	Entered by operator by selection of correct county from drop-down menu on display.
Crime arrested for	Entered by operator by selection of correct county from drop-down menu on display. Options include: DUI Physical control, .02 minor law,

	commercial driver's license, officer self-test, administrative procedure Other, assault, domestic violence, boating under the influence, homicide by watercraft, assault by watercraft
Collision involved?	Yes or No selected from display screen by operator.
Subject drinking at specific drinking establishment?	"YES" selected: Operator will be able to type in any part of the name of the establishment (example: Joe's Bar or Joe) a list will populate with every listing from the state with the typed information and the operator will be able to select the appropriate location. Once the selection is made, the appropriate liquor license number is recorded in the database based on the data supplied by the WA State Liquor Control Board. "NO": A dropdown menu of generic locations will display all other options such as unknown location, private residence, banquet hall, etc. Operator will be required to select one of those options.
PBT given?	Yes or No selected from display screen by operator. If "Yes" selected, the operator will have to enter the PBT result and PBT time in 24 hr time.
Scan operator card?	Yes or No selected from display screen by operator. "Yes" selected: The instrument will then require the operator permit card to be scanned. Once scanned, the operator's Last/First/MI and agency ORI code, provided at time of certification, will be logged into instrument and the name will be displayed on the printed document.

	"No" selected: The operator will be required to enter the above information via the keyboard.
Subject Driver's License State	Select from the drop-down menu the state of the subject's driver's license. If "Washington" selected: The instrument will provide the option of scanning the WA State driver's license and the subject's name, DOB, gender, and driver's license number will be logged into the database. The name and DOB will also print on the final breath test document. Any other state selected: The instrument will require the above information to be entered via the keyboard.

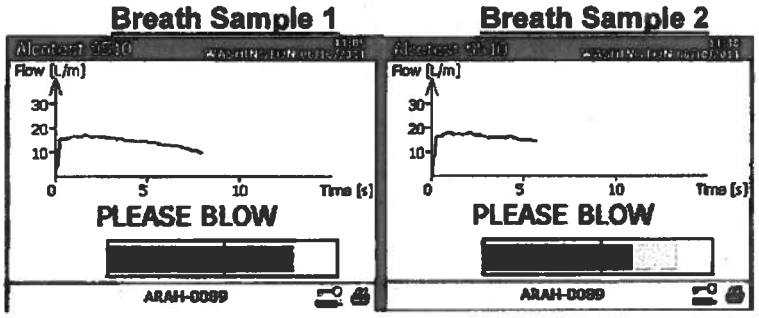
Sampling Parameters and Acceptance Criteria

The Draeger instrument software is designed to accept breath samples which meet the following criteria:

- Start flow rate is at least 8.0 liters/minute
- Minimum/Stop flow rate is at least 4.0 liters/minute
- Minimum blow time of 5.0 seconds
- Minimum breath volume of 1.5 liters
- Plateau recognition if the concentration increases ≤ 4% in one second
- All four of the test results (IR and EC from each of the two breath samples) must be between ± 10% of the mean of all four test results (truncated to 3 digits after the decimal). This criteria is only required if all four test results are greater than or equal to 0.01 g/210L.

The following graphic displays on the screen during the breath sampling phases to assist the operator in obtaining a proper sample. The "PLEASE BLOW" breath volume bar will monitor the volume and time of the sample, and when all criteria are met, the bar will be filled to the line in the middle of the volume bar indicating that the minimum parameters have been satisfied. The bar will continue to fill as long as the subject continues to provide the sample to ensure a deep lung sample is obtained. The next graphic is for second subject sample. When this appears, the volume bar will have a portion that has been grayed out. This is the volume of the prior sample and if the operator can coach/instruct the subject to similar volume by having them provide a

sample until the blue volume bar fills the grayed out volume. The intent of this mechanism is to eliminate samples which are outside of the criteria of ±10% of the mean of all four test results.



Mouth Alcohol Detection

The detection of mouth alcohol is based on the analysis of the infrared's alcohol vs. time profile taken during the subject's sample. A normal profile is characterized by a sharp increase in the concentration at the beginning of the blow followed by a more moderate increase in the concentration until the end of the provided breath. In the case of mouth alcohol the profile changes considerably. There will decreasing concentration and thus a negative slope. The Draeger employs an algorithm that can identify the various sudden changes (positive or negative) in the slope of the breath curve that are associated with mouth alcohol. Once identified, the instrument aborts the test and displays a status message of "Invalid Sample". The operator must then complete a new observation period before another test may be performed.

Detection of interfering substances

The 9.5 µm operating range of the Draeger's infrared sensor is virtually free from the influence of compounds such as acetone, toluene, and acetaldehyde (some of the most frequently mentioned interfering compounds). As mentioned earlier, the electrochemical (fuel cell) detection system is specific to alcohol. As a result, the Draeger has been programmed to detect interfering compounds by a comparison of the infrared vs. electrochemical readings in the same sample. The EC results must be within 0.008g/210L or 10% of the infrared reading, whichever is greater. Any result outside of one of these tolerances will generate a status message of "Interference Detected".

Quality Assurance Procedure

The Quality Assurance Procedure (QAP) as identified in the BTP Technical Manual is programmed into the Draeger instrument. The steps for the entire QAP are accessed via a technician USB key, and may only be changed by authorized technicians. The QAP must be completed in full before the instrument can be placed into service for evidential tests. If any part of the QAP is not completed, the instrument will not allow a test to be run by an operator. The date of the QAP is recorded on the Draeger Alcotest 9510 Calibration/Adjustment Record (generated by the instrument) as well as the final printed evidential breath test documents. Each QAP is valid for 12 months, and once this date expires, the instrument will place itself out of service and no evidential test may be completed until the new QAP has been completed.

Internal Standard Function

This function is performed with each breath test. The analytical process is virtually identical to that of an actual breath alcohol analysis. The IR-detector related algorithm is the same as that of a breath test which produces a quantitative reading. A very specific and consistent amount of the radiated IR energy from the IR Source passing through the absorption chamber is attenuated. This resembles the effect that alcohol vapor has in the absorption chamber thus; the instrument computes the drop in IR energy to a corresponding alcohol concentration reading.

Dry Gas as External Standard

The external standard function of the Draeger is done using an ethanol dry gas which is produced by Calgaz Inc. for Draeger Safety Diagnostics Inc. The pressurized gas is connected to the back of the Draeger and is secured in a locked compartment. Two tanks will be fitted to each instrument and the ethanol standard will have a nominal value of 0.08 g/210L. The instrument is designed to analyze the dry gas sample between the two subject samples. The instrument will analyze the sample using both the infrared detector and electrochemical functionality and report the final result if they fall between the mandatory guidelines of 0.072-0.088 g/210L, inclusive. If either technology does not report within this range, the instrument will stop the testing process and place itself out of service with a message of "External Standard Out of Range". Each dry gas standard has an expiration date which falls three years from the date it was manufactured. This date is entered along with the lot number for each tank during the cylinder changing process. Once a cylinder has expired, or if the cylinder does not have sufficient pressure, the instrument automatically examines the expiration date and pressure of the second tank. If the second tank meets the minimum criteria, the instrument automatically will switch to the second tank. If neither tank meets the

mandatory criteria above, the instrument will display an error of "dry gas cylinder error", and the instrument will not allow an evidential test to be completed.

With all pressurized ethanol gasses, the ambient air pressure has the ability to influence the result of the analyzed gas. This is a result of the gas expanding according to the atmospheric pressure. The Draeger has a built in pressure sensor which will compensate for any such atmospheric conditions. This ensures that the ambient pressure does not interfere with the proper reading of the dry gas. The pressure sensor will be maintained through regular checks by BTP personnel using an independent barometer per procedures located within the BTP Technical Manual.

Radio Frequency Interference

Because of the unique design of the Draeger instrument there is no susceptibility to radio frequency interference (RFI). Draeger Safety Diagnostics Inc. had testing completed by an independent laboratory confirming the device is not affected by RFI.

Status Messages

The status messages, often referred to as error codes, are found within the manufacturer's technical manual. These messages are what may be expected when an error occurs. Anytime one of these messages is displayed by the instrument, it is logged within the database and the instrument will not allow a complete evidential test until the message has been resolved.

Conclusion

In conclusion, the software versions listed herein are deemed to function as required, meeting all criteria of the Revised Code of Washington and Washington Administrative Code. The instrument and software are fit for purpose and valid performance will be ensured through our technical program and its quality assurance procedures.

KLD:kld

I CONCUR WITH SGT. DENTON'S FINDING OF ACCEPTABILITY AND RECOMMENDATION FOR APPROVAL. THE SOFTWARE IS FIT FOR PURPOSE AND WILL PERFORM SUITABLY. FORWARD TO QA MANAGER E. NEILSON.

R SHORE 9/30/14

I concur with this software/firmware assessment.

10/1/2014
ERIK NEILSON

The multiple software components described and listed above for the Draeger Alcotest 9510 evidential breath test instruments are approved for use. Recommendations on any actions required following software upgrades/changes are also approved.

FIONA COUPER 10-4-14